III. REMARKS

A. Amendments to the Specification and Drawings

Figure 2 has been amended to add "15" and a line pointing from 15 to upper compartment 14.

Paragraph **[0024]** has been amended to add a statement that "The upper compartment **14** is substantially filled with aqueous suspension formulation **15**."

Basis for the amendments to the specification and drawings can be found in paragraph **[0021]**, which states "the present invention provides an article of manufacture comprising a vial having (a) a first chamber that is substantially filled with an aqueous suspension formulation as described herein . . ." Paragraph **[0024]** states that the "upper compartment **14** corresponds to the 'first chamber.'"

Applicant submits that neither the amendment to the specification nor to Figure 2 introduce new matter to the application.

B. Claim Amendments

Claim 4 has been canceled. This claim depends from claim 1.

C. Rejection of Claim 4, Under 35 U.S.C. §112, Second Paragraph

Claim 4 was rejected under 35 U.S.C. §112, second paragraph "as being indefinite for failing to particularly point out and distinctly claims the subject matter which applicant regards as the invention." The Office Action specifically stated that this particular claim fails to meet the definiteness requirement because it contains the trademark "Act-O-Vial." Claim 4 has been canceled. Therefore, Applicant submits that this rejection is now moot.

D. Rejection of Drawings, Under 37 C.F.R. §1.83(a)

The drawings were objected to under 37 C.F.R. §1.83(a) for failure to "show every feature of the invention specified in the claims." The Office Action stated that the "aqueous medium of claim 1 must be shown or the feature(s) canceled from the claims(s)." Applicant respectfully notes that the "aqueous medium" of claim 1 is a

component of the "aqueous suspension" element of claim 1. Therefore, Applicants submits that the drawings conform with 37 C.F.R. §1.83(a) if they were amended to indicate the location of the aqueous suspension element.

Applicant respectfully submits that the drawings as filed depict an embodiment of a vial suitable for use in the article of manufacture of claim 1, not the article of manufacture itself. Claim 1 clearly states that the "first chamber" of the vial is "substantially filled with a parenterally deliverable aqueous suspension." Paragraph [0024] defines the "first chamber" as the upper compartment 14 in the vial illustrated in Fig. 2. In view of the above, Applicant submits that the drawings conform with §1.83(a) as filed. However, in order to further clarify the position of the aqueous suspension when the vial illustrated in the drawings is used in the article of manufacture of the present invention, Applicant has amended the drawings and specification to show that aqueous suspension 15 is present in the upper compartment 14 illustrated in Fig. 2.

For reasons provided above, Applicant submits that the drawings conform with 37 C.F.R. §1.83(a).

E. Rejection of Claims 1-4, Under 35 U.S.C. §103(a), over U.S. Patent No. 4,089,432 (Crankshaw *et al.*)

Claims 1-4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Crankshaw *et al.* The Office Action stated that Crankshaw *et al.* discloses the "structure of a vial 11," but "fails to disclose that the upper chamber is filled with an aqueous medium and the lower chamber is filled with a gaseous medium." The Office Action goes on to state that it would have been obvious to "provide a medicament in solution in one chamber, separated from a degratory gaseous medium (absent any lyophilized medicament) in the other chamber, as claimed." Applicant respectfully submits that it would not have been obvious to one of ordinary skill in the art to modify the teachings of Crankshaw *et al.* to make the article of manufacture of the present invention, in view of the following.

The MPEP states that:

> "In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents." MPEP, rev. 2, May 2004 citing *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

Applicant respectfully submits that in order to support the obviousness rejection in this case the Office Action relies on an alleged equivalence of the aqueous suspension elements in one chamber and gaseous medium elements in the other chamber of the vial of claim 1 to the disclosure of Crankshaw *et al.* of the use of the presence of a lyophilized powder of a medicament in one chamber from a solvent in the second chamber. The Office Action states that in Crankshaw *et al.* "the purpose of the two-compartment vial is to provide a stable storage solution wherein two substances, which may include a medication, may be stored completely independently from one another." However, Applicant submits that this statement is an overgeneralization of the teachings of that particular reference, one impermissibly based upon Applicant's disclosure.

The article of manufacture of claims 1-4 is also nonequivalent to the device and use of the device disclosed or suggested by Crankshaw *et al.* because the present claimed article operates in a different way to achieve a different result. Stability of the medicament in the prior art device is maintained by keeping the chamber in which it is placed dry and free of the solvent so that the medicament does not come into contact with the solvent in the other chamber until used. Thus, stability of a medicament, which is unstable in a particular solvent, can be maintained until needed. In contrast, the present article of manufacture maintains the stability of the drug by minimizing the amount of oxidation of an aqueous suspension of the drug. Specifically, the aqueous suspension substantially fills the first chamber of the vial to minimize headspace and contact with oxygen, as well as separating it from a gaseous medium in the second chamber. Applicant respectfully submits that it would not have been obvious to one of ordinary skill in the art to modify the teachings of Crankshaw *et al.* to make the article of manufacture of the present invention.

In view of the above, Applicant respectfully submits that the subject matter of claims 1-4 is patentable under 35 U.S.C. §103(a) in view of Crankshaw *et al.* Applicant respectfully requests that this rejection be withdrawn.

F. Rejection of Claims 5-23, Under 35 U.S.C. §103(a), over Crankshaw *et al.* in view of U.S. Patent No. 6,481,435 (Hochrainer *et al.*)

Claims 5-23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Crankshaw *et al.* in view of Hochrainer *et al.* These claims are directed to the article of manufacture of claim 1 wherein the article contains a particular gaseous medium or particular aqueous suspension elements. The Office Action acknowledged that Crankshaw *et al.* fails to teach "the contents and relative formulations of the medicament within the vessel." It alleged that the additional elements are disclosed by Hochrainer.

Applicant respectfully submits that Crankshaw *et al.* fails to teach or suggest the article of manufacture of claim 1, for reasons given in the preceding section above. Specifically, Crankshaw *et al.* discloses a two chamber vial containing a medicament in the form of a lyophilized powder in one chamber and a liquid solvent in the other chamber. That reference fails to teach or suggest a vial having a first chamber that is substantially filled with an aqueous suspension and a second chamber that contains a gaseous medium, all of which are elements of claim 1.

Hochrainer discloses an apparatus which includes a container in the form of a two-chamber cartridge in which an active ingredient is stored in one chamber and a solvent is stored in the other chamber until solvent and active ingredient are combined prior to administration by inhalation. The reference also discloses a wide range of active substances suitable for administration using the apparatus. However, neither Hochrainer viewed alone or in combination with Crankshaw *et al.* teach or suggest the same elements of the article of manufacture of claim 1 missing from Crankshaw *et al.* alone, specifically, a vial having a first chamber that is substantially filled with an aqueous suspension and a second chamber that contains a gaseous medium.

In view of the above, Applicant respectfully submits that the subject matter of claim 1 and of all claims which depend from the claim, including claims 5-23, is

patentable under 35 U.S.C. §103(a) over Crankshaw *et al.* in view of Hochrainer. Therefore, Applicant respectfully requests that this rejection be withdrawn.

IV. SUMMARY

For reasons set forth above, Applicant respectfully submits that all of the presently pending claims (i.e., claims 1-23) are in condition for allowance. Issuance of all the claims is, therefore, requested. The Examiner is invited to contact the undersigned at the telephone number given below, should she wish to discuss any of the above.

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